UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT TACOMA

UNITED STATES OF AMERICA, *et al.*, Plaintiffs, *Ex rel.*, JAMIE SIEGEL, M.D., Plaintiff-Relator, v. NOVO NORDISK, INC., Defendant.	CASE NO. C23-5459 BHS ORDER

THIS MATTER is before the Court on plaintiffs[1] Siegel and Washington's motion to exclude the testimony of defendant Novo Nordisk Inc. (NNI)'s expert witness, Dr. Marilyn Manco-Johnson, Dkt. 421.

[1] The Court refers to plaintiff relator Siegel and intervenor plaintiff State of Washington as "Washington" for clarity and ease of reference, unless the context requires otherwise.

Dr. Manco-Johnson is a board-certified hematologist with fifty years of experience treating hemophilia. She has treated patients, including those with the inhibitor antibodies, with NovoSeven and alternative hemophilia treatments developed by other pharmaceutical companies. Dkt. 422-2; *see* Dkt. 250 at 6 (NovoSeven was intended to treat hemophilia patients with inhibitors).

Dr. Manco-Johnson's report describes the history, development, and standard of care applicable to hemophilia treatments. Dkt. 422-2 at 5, 9. She opines that from 2005 to 2015, the period relevant to this case, the prophylactic and high dose usage of NovoSeven was "safe, effective, and accepted by doctors . . . for certain hemophilia patients with inhibitors." *Id.* at 5. NovoSeven was considered "clinically appropriate and an accepted method of treatment." *Id.* at 29, 35.

Washington challenges Dr. Manco-Johnson's report as irrelevant because the report does not "mention or analyze the medical necessity" of NovoSeven. Dkt. 421 at 5. It further argues that her testimony about the standard of care is irrelevant because this "is a case about whether illegal means were used to cause the government to pay for a product that was not medically necessary, as defined by standards particular to the Washington Medicaid program." Dkt. 470 at 5. Washington also argues that Dr. Manco-Johnson should be precluded from testifying about the use of and reference to compendia because her report does not "mention or evaluate any compendia." Dkt. 421 at 8.

A qualified expert may testify in the form of an opinion or otherwise only if the proffered testimony is both relevant and reliable. Fed. R. Evid. 702; *Teradata Corp. v. SAP SE*, 124 F.4th 555, 566 (9th Cir. 2024) (citing *Daubert v. Merrell Dow*

Pharmaceuticals, Inc., 509 U.S. 579, 589 (1993)). Rule 702 and *Daubert* impose on the district court a "gatekeeping" duty to ensure that opinion testimony is relevant and reliable, and an expert's opinion should be excluded if it does not have a reliable foundation or if it is not based in the knowledge and experience of the relevant discipline. *Sonneveldt v. Mazda Motor of Am., Inc.*, 2024 U.S. App. Lexis 32836, *3 (9th Cir. Oct. 21, 2024) (citing *Primiano v. Cook*, 598 F.3d 558, 564-65 (9th Cir. 2010)). "Expert opinion testimony is relevant if the knowledge underlying it has a valid connection to the pertinent inquiry. And it is reliable if the knowledge underlying it has a reliable basis in the knowledge and experience of the relevant discipline." *Surgical Instrument Serv. Co. v. Intuitive Surgical, Inc.*, 2024 U.S. Dist. Lexis 81690, *5 (N.D. Cal. March 31, 2024) (quoting *Alaska Rent-A-Car, Inc. v. Avis Budget Grp., Inc.*, 739 F.3d 960, 969 (9th Cir. 2013). When an expert meets the Rule 702 threshold, "the expert may testify and the jury decides how much weight to give that testimony." *Primiano*, 598 F.3d 558 at 565.

First, the Court agrees that Dr. Manco-Johnson's report fails to mention or evaluate any compendia. Any such testimony will therefore be excluded.

Next, Dr. Manco-Johnson will be precluded from testifying as to whether illegal means caused the off-label use of NovoSeven. Her report does not contain any opinions on this issue.

Finally, the Court concludes that the standard of care applicable to NovoSeven and its medical appropriateness is relevant to this case. Although she does not use the term "medical necessity," Dr. Manco-Johnson opines that NovoSeven was considered safe, effective, and accepted by doctors. Washington raises both medical necessity and

acceptance in its briefing. *See, e.g.,* Dkt. 433 at 18, 20. While it suggests the standards for medical acceptance and necessity are distinct, *id.* at 18, this argument goes to the weight, not admissibility, of Dr. Manco-Johnson's testimony.

Washington has even argued that its claims depend on the alleged unlawful kickbacks, not medical necessity. *See* Dkt. 405 at 9–10, 13–14. There is no dispute that after several doctors, including Dr. Thompson and the 2009 Hemophilia Working Group, reviewed NovoSeven for medical necessity, Washington Medicaid paid for the use of NovoSeven during the relevant period. Dkt. 480 at 1–2. Washington has even conceded that this payment is evidence of medical necessity. Dkt. 405 at 14.

The Court has authorized an adverse inference instruction that permits the jury to infer that the lost or destroyed HCA records likely show that reviewers approved NovoSeven because it was medically necessary. *Id.* at 56. It is possible the jury could conclude that neither Dr. Manco-Johnson and Dr. Thompson nor the 2009 Hemophilia Working Group followed the regulatory hierarchy of evidence in determining medical necessity. This makes Dr. Manco-Johnson's opinion on NovoSeven's medical appropriateness, acceptance, and standard of care relevant and admissible.

Dr. Manco-Johnson has sufficient expertise and experience treating hemophilia patients with inhibitors with NovoSeven for on- and off-label purposes. Her knowledge, background, and testimonial opinions concerning hemophilia and the evolution of treatment modalities over decades satisfy the requirement in Rule 702 that her testimony will assist the jury in understanding the evidence and determining facts in issue. Her testimony will be largely permitted because she is a qualified expert in the medical field

through education, training, experience, knowledge, and skill, her report is based on sufficient facts or data, and her opinions are the product of the reliable application of principles and methods.

The Court expects Dr. Manco-Johnson's testimony on these matters will not take extensive trial time.

Washington's motion to exclude Dr. Manco-Johnson's opinion, Dkt. 421, is therefore **GRANTED in part and DENIED in part**.

IT IS SO ORDERED.

Dated this 15th day of July, 2025.

BENJAMIN H. SETTLE
United States District Judge